public record.[1238] *See* 60 FR 41565, n.116 and n.117. The only other reference to the nasal spray in the Jurisdictional Analysis is at 60 FR 41569, where again the Agency relied on a statement offered at the August 1994 advisory committee meeting, not on the NDA itself. 60 FR 41569 and n.126. Therefore, all the materials relating to the nasal spray on which the Agency relied in the to the Jurisdictional Analysis are in the public docket.

As for the five NDA's the Agency cited in footnotes 62 and 64 of the Jurisdictional Analysis, the Agency put into the administrative record an extensive summary, prepared at the time of approval, for each of these NDA's.[1239] Given the volume of materials that make up each of these NDA's, and the limited purpose for which the Agency was relying on them, *see* 60 FR 41549–41550, it was appropriate for the Agency to include only the summaries. *See National Ass'n of Pharmaceutical Mfrs. v. Department of Health and Human Services*, 586 F. Supp. 740, 755-756 (S.D.N.Y. 1984). A complete NDA can run into the tens of thousands of pages, particularly when one includes the records which must be kept for each patient enrolled in each clinical trial. Putting this volume of materials on the record in this instance would serve no useful purpose. Instead, the Agency included on the record the summaries it prepared in anticipation of approving each of these smoking cessation products as safe and effective. The summaries themselves are peer reviewed within the Agency to ensure that they thoroughly and accurately discuss each of

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[1238] Kramer ED, Transcript of testimony before the Drug Abuse Advisory Committee (Aug. 1, 1994). *See* AR (Vol. 9 Ref. 116).

FDA Drug Abuse Advisory Committee Background Information, Joint Abuse Liability Review of Nicotine Nasal Spray (Aug. 1, 1994). *See* AR (Vol. 9 Ref. 117).

[1239] NDA 20-076 Habitrol (CIBA); NDA 20-150 Nicotrol (Kabi); NDA 19-983 ProStep (Elan); NDA 20-165 Nicoderm (Alza); NDA 20-066 Nicorette (Merrell Dow). *See* AR (Vol. 6 Refs. 62-63).

the studies on which the approval is based. They generally provide more detail about a sponsor's underlying clinical data and methodology than one would expect to find in published peer-reviewed medical literature.

As discussed in greater detail, below, notice is sufficient under the APA when it provides the public a "reasonable opportunity" to participate in the proceeding. *Forester v. Consumer Product Safety Commission,* 559 F.2d 774, 787 (D.C. Cir. 1977). This is not an instance in which the Agency failed to explain the technical basis for its position, failed to disclose its reasoning, or otherwise failed to identify and make available the data on which it relied to reach a particular conclusion. *See Connecticut Light and Power Co. v. Nuclear Regulatory Commission,* 673 F.2d 525, 530-532 (D.C. Cir. 1982). Rather, the summaries the Agency placed on the public docket provided detailed access to the pivotal data on which the Agency relied in approving these NDA's. Even more, the summaries identified the very data on which FDA relied in this proceeding to support the position that nicotine replacement therapy helps reduce withdrawal symptoms in smokers trying to quit, and that participants enrolled in clinical studies of nicotine replacement therapy demonstrated addiction to nicotine. 60 FR 41453, 41459–41460. This is also the data on which the Agency relied to support the position that the efficacy of nicotine replacement therapy shows that most smokers are indeed addicted to nicotine. *Id.* at 41459. Thus, these summaries provided the public with ample access to the information needed to comment meaningfully on the Agency's position.

b. The Agency's Reference to Nineteen Smoking Cessation Studies

FDA prepared Appendix 1 to the Jurisdictional Analysis to provide the public with background materials supporting the Agency's scientific judgments with respect to nicotine pharmacology. In that Appendix, the Agency discussed a number of smoking cessation studies, including 19 studies submitted in support of the NDA's for Habitrol, Nicotrol, ProStep, Nicoderm, Nicorette (4mg), Nicorette (2 mg), and nicotine nasal spray.[1240]

The Agency referenced these studies as yet another way to demonstrate that nicotine obtained from tobacco products produces dependency. The efficacy of nicotine replacement therapy in reducing withdrawal symptoms strongly suggests this conclusion.

To further demonstrate the point, the Agency supplied the public with efficacy data for each of the 19 studies. The incorporation in Appendix 1 of the relevant data from these studies in itself allowed for a reasonable opportunity to comment on the Agency's use of the studies. Again, the fact that the Agency has approved these products as smoking cessation aids, because of their effectiveness in relieving withdrawal from nicotine, supports the Agency's point that nicotine from certain tobacco products causes dependency.

In addition to providing in the Appendix itself the data on which FDA relied, the Agency relied on studies that have been widely reported on in the medical and scientific literature. For example, each of the studies the Agency cited from the NDA's for Nicorette (2mg) and nicotine nasal spray have been reported on in "refereed" or peer-

[1240] *See* appendix 1 to Jurisdictional Analysis, at 62-85. *See* AR (Vol. 1 Appendix 1).

reviewed journal articles.[1241] *See National Ass'n of Pharmaceutical Mfrs.*, 586 F. Supp. at 756 n.45 ("The public availability of information not included in the administrative record is a factor to be considered in determining whether the record is inadequate for failing to include it") (citations omitted). Thus, to the extent Appendix 1 or the administrative record itself did not provide the public with enough information to comment on the Agency's analysis, the public had easy access to journal articles authored by the individuals who designed and conducted each of the studies.

Finally, with respect to all but the five studies referenced from the NDA's for Nicorette (2mg) and nicotine nasal spray, the public had access to the "backup" for the data on which the Agency relied through the NDA summaries the Agency included on the public docket. For the Agency to put on the record further documentation to support this "backup" would have been excessive, given the limited purpose for which the Agency relied on these studies.

[1241] *See* Christen AG, McDonald JL, Olson BL, Drook CA, Stookey GK, "Efficacy of a nicotine chewing gum in facilitating smoking cessation," *Journal of the American Dental Ass'n* 1984; 108: 594-597. *See* AR (Vol. 711 Ref. 25).

Jarvis MJ, Martin RAW, Russel MAH, Feyerabend C, "Randomised controlled trial of nicotine chewing-gum, *British Medical Journal* 1982; 285:537-540. *See* AR (Vol. 711 Ref. 26).

Schneider NG, Olmstead R, Mody F, Doan K, Franzon M, Jarvik ME, Steinberg C, Efficacy of nicotine nasal spray in smoking cessation: a placebo-controlled, double-blind trial, *Addiction* 1995; 90:1671-1682. *See* AR (Vol. 711 Ref. 27).

Sutherland G, Stapleton JA, Russel MAH, Jarvis MJ, Hajek P, Belcher M, Feyerabend C, Randomised controlled trial of nasal nicotine spray in smoking cessation, *Lancet* 1992; 340:324-29; *See* AR (Vol. 348 Ref. 5511).

Hjalmarson A, Franzon M, Westin A, Wiklund O, Effect of nicotine nasal spray on smoking cessation, *Archives of Internal Medicine* 1994; 154:2567-2572. *See* AR (Vol. 711 Ref. 28).

The Agency, then, referenced 19 studies to prove a single point. The public docket included detailed summaries, prepared for purposes of approving a drug product as safe and effective, of 14 of the 19 studies. For the tobacco industry to claim that it lacked adequate data with which to challenge the Agency's conclusion, which could have been supported by far fewer than 19 studies, is unreasonable.

In sum, the complaint that FDA did not put on the public docket the "actual studies" used to support these NDA's is misplaced. When FDA relied on a specific NDA, it put a detailed summary of the NDA in the public docket; and when FDA relied on particular NDA studies, it provided the public with the data from those studies in the appendix itself. The Agency also took care to rely on studies which have been widely reported on in the medical and scientific literature. The comment from the tobacco industry that the Agency in this instance withheld crucial information is tantamount to arguing that for each journal article on which the Agency relies, it must also include in the record all the raw data discussed or analyzed in the article. This is a level of disclosure that exceeds reason, not to mention the basic tenets of notice under the APA. The Agency, therefore, is not persuaded that the industry, or any other interested person, was deprived of a meaningful opportunity to comment on the Agency's reference to certain smoking cessation studies or certain NDA's.

5. The Agency's Reliance in the Final Jurisdictional Determination on New Materials

In an ordinary informal rulemaking proceeding, the final administrative record must contain the proposed rule, including all information that the Commissioner identifies or files with the proposal, all comments received on the proposal, including all information

submitted as part of the comments, and the notice promulgating the final regulation, including all information that the Commissioner identifies or files with the final regulation. 21 CFR 10.40(g). An agency may rely on information and data that was not included at the proposal stage that expands on or confirms information in the proposal or addresses alleged deficiencies in the pre-existing data, provided that no prejudice is shown.[1242] Otherwise, "[r]ulemaking proceedings would never end if an Agency's response to comments must always be made the subject of additional comments." *Community Nutrition Inst.*, 749 F.2d at 58. Accordingly, the Agency has cited in the final jurisdictional determination a small amount of information that is needed to respond fully to comments or that otherwise supplements the information contained in or filed with the proposal. These documents include published scientific articles, reference texts, a Centers for Disease Control and Prevention memorandum and supporting data, letters to tobacco industry counsel, an abstract that the tobacco industry asked to include in the record, a small number of publicly released tobacco company documents, Congressional hearing transcripts, and newspaper articles. The Agency has placed this cited information in the administrative record for the jurisdictional determination.

[1242] *See, e.g., Personal Watercraft v. Dep't of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995) ("Agencies may develop additional information in response to public comments and rely on that information without starting anew unless prejudice is shown."); *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) ("[C]onsistent with the APA, an agency may use 'supplementary' data, unavailable during the notice and comment period, that expands on and confirms information contained in the proposed rulemaking and addresses alleged deficiencies in the pre-existing data, so long as no prejudice is shown."); *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57-58 (D.C. Cir. 1984) (agency may rely on information that "expanded on and confirmed" information in the proposal and addressed alleged deficiencies in the record); *see also* K. Davis, *Administrative Law Treatise*, § 7.3 (3d ed. 1994).

B. ADEQUACY OF THE NOTICE

Two industry comments argued that the public's participation in the jurisdictional determination, as well as in the rulemaking process, has been frustrated because the Agency presented a "one-sided" view of the Jurisdictional Analysis and the Proposed Rule. Although neither comment disagreed with the Agency's use of notice and comment-type procedures to reach a jurisdictional determination, both comments claimed that FDA failed to satisfy the APA's notice requirement for informal rulemaking because the Agency neither disclosed nor discussed the supposedly "large body" of information "that is inconsistent with, or otherwise not supportive of, the Proposed Rule."[1243] Further, the Agency did not, in their view, provide a "reasoned explanation" for departing from past precedent on the issue of whether FDA should regulate all cigarettes and smokeless tobacco.[1244]

These comments provided no legal authority to support the proposition that, assuming the Agency is bound here by APA precedent governing informal rulemaking, the Agency was required at the notice stage to anticipate all challenges to its reasoning, and should have attempted in its notice to answer those challenges. Rather, at the notice stage of a rulemaking proceeding, the Agency's obligation is to include sufficient detail to allow for meaningful and informed comment. *See American Medical Ass'n v. Reno*, 57 F.3d

[1243] Joint Comments of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 15. *See* AR (Vol. 535 Ref. 96). *See also* Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 33-38. *See* AR (Vol. 526 Ref. 95).

[1244] Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 38-39. *See* AR (Vol. 526 Ref. 95).

1129, 1132 (D.C. Cir. 1995); *Home Box Office, Inc. v. Federal Communications Commission*, 567 F.2d 9, 35-36 (D.C. Cir.), *cert. denied*, 434 U. S. 829 (1977).

More specifically, in an informal rulemaking proceeding, the APA requires public notice of an Agency's intention to issue a regulation. 5 U.S.C. 553(b). The notice must include "reference to the legal authority under which the rule is proposed," and "either the terms or substance of the Proposed Rule or a description of the subjects and issues involved." 5 U.S.C. 553(b)(2) and (b)(3). FDA's own regulations require that a notice of proposed rulemaking include "a preamble that summarizes the proposal and the facts and policy underlying it, . . . all information on which the Commissioner relies for the proposal, . . . and cites the authority under which the regulation is proposed." 21 CFR 10.40(b)(vii).

Under case law construing section 553 of the APA, notice of informal rulemaking must be "sufficiently descriptive of the 'subjects and issues involved' so that interested parties may offer informed criticism and comments." *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 48 (D.C. Cir.) (*en banc*), *cert. denied* 426 U.S. 941 (1976). Notice is sufficient under the APA "if it affords interested parties a reasonable opportunity to participate in the rulemaking process." *Forester*, 559 F.2d at 787; *accord State of South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. 1983), *cert. denied*, 465 U. S. 1080 (1984). And, insofar as the proposal to regulate relies on a technical study or specific data essential to an understanding of the rule, the notice should disclose this information to the extent needed to allow for "meaningful comment." *Connecticut Light and Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525, 530-531 (D.C. Cir.), *cert. denied*, 459 U. S. 835 (1982).

In this instance, the Agency's Jurisdictional Analysis met both the APA's notice requirements (as interpreted by prevailing case law), as well as FDA's own procedural requirements. The Agency by any standard "fulfilled its obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." *Air Transport Ass'n of America v. Civil Aeronautics Board*, 732 F.2d 219, 225 (D.C. Cir. 1984) (quoting *Home Box Office, Inc.*, 567 F.2d at 36).

1. The Agency Provided Adequate Notice of the Key Legal and Factual Issues

Although the APA's notice requirements could have been met by a far briefer presentation, the Agency chose to supply the public with a discussion of its Jurisdictional Analysis that explored in full the wide range of factual and legal issues presented. In doing so, the Agency discussed a number of the issues that the industry commenters claimed were missing from the Jurisdictional Analysis.

The comments contended that the Agency failed to discuss past instances in which it declined to exercise jurisdiction over cigarettes and smokeless tobacco products, including FDA's response to a 1977 citizen petition. One comment in particular insisted that such a discussion would have alerted the public to the idea that Congress enacted preemptive legislation in reliance on FDA's past pronouncements, legislation which the comments argue bars FDA from regulating these products.

The Agency acknowledged in its Jurisdictional Analysis that it has in the past refrained from exercising jurisdiction generally over all cigarettes and smokeless tobacco products (provided claims were not made for the product). 60 FR 41482 n.5. Among other things, the Agency referred readers to the published decision in *Action on Smoking*

and Health (ASH) v. Harris, 655 F.2d 236 (D.C. Cir. 1980). That decision reviewed the Agency's rejection of the 1977 citizen petition, which one comment claimed the Agency "conscientiously avoid[ed]" in the Jurisdictional Analysis in order to "mislead[]" the public.[1245] Not only does the *ASH* opinion discuss the petition and the Agency's position at that time with respect to exercising jurisdictional generally over cigarettes, it also recounts for the reader the Agency's historical position on the issue. 655 F.2d at 237-241. Moreover, the Agency placed in the administrative record copies of documents in which FDA declined to exercise jurisdiction, including FDA's response to ASH's 1977 citizen petition.[1246]

In addition, the Agency attached as part of an appendix to its Jurisdictional Analysis, copies of the Commissioner's testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on March 25, 1994.[1247] At the outset, Commissioner Kessler stated:

> Although FDA has long recognized that the nicotine in tobacco products produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. . . . With certain exceptions, we have not had sufficient

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[1245] Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 35. *See* AR (Vol. 526 Ref. 95).

[1246] *See* Letter from Kennedy D (FDA) to Banzhaf J (ASH) (Dec. 5, 1977). *See* AR (Vol. 503 Ref. 8882) (denial of 1977 petition).

Letter from Goyan JE (FDA) to Banzhaf J (ASH) (Nov. 25, 1980). *See* AR (Vol. 503 Ref. 8881).

Public Health Cigarette Amendments of 1971, *Hearings before the Consumer Subcommittee of the Committee on Commerce, U.S. Senate*, 92d Cong., 2d Sess. at 239-246. *See* AR (Vol. 503 Ref. 8894).

[1247] *See* appendix 7 to the Jurisdictional Analysis. *See* AR (Vol. 1, Appendix 7).